

REMARKS

Claims 1-134 are pending. Claims 1-66, 74, 82-95, and 97-134 have been withdrawn from consideration. Claims 1-66 are canceled without prejudice for future prosecution. By this Amendment, claims 67, 70, 71, 73, 75, 77-80, and 96 are amended, and the specification is amended as indicated. Claims 67-73, 75-81, and 96 have been rejected under 35 U.S.C. §112, as discussed below. Claims 67-73, 75-78, and 80-81 have been rejected over the prior art, as discussed below. Claims 79 and 96 has not been rejected over the prior art and are therefore understood to be free of the prior art.

The term "transcription modulating factor" was amended to "transcription factor" to more clearly use terminology recognized by persons of ordinary skill in these arts. The term "cancer condition" was amended to "cancer" to more clearly use terminology recognized by persons of ordinary skill in these arts. Further, the claims were amended to further specify that the detection of an autoimmune response against the transcription factors indicates the type of the cancer condition.

As indicated in the Office Action, at ¶2, the undersigned, in the interview of February 25, 2005, agreed to withdrawal of claims 82 and 88 to expedite prosecution. There has been no admission that these claims lack enablement or utility. The Examiner is thanked for rejoining certain of the claims to now-elected Group 37 in order that the rejoined claims may be examined. The term "Hey/HRT" is intended to have a scope that embraces all members of the Hey/HRT family.

The Office Action, at ¶3, points out that allowance of linking claim 67 will result in rejoinder and examination of the dependent claims of claim 67. The Applicants are in agreement that such rejoinder is called for.

Response to rejections for indefiniteness under 35 U.S.C. 112 ¶2

Claim 67-73, 75-81, and 96 were rejected under 35 U.S.C. 112 ¶2, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In response, claim 67 was amended to recite a positive process step that relates to the preamble, with the amendment including language indicated by the Examiner. Further, the term "transcription modulating factor" was amended to "transcription factor", as discussed above.

Response to rejections for lack of enablement under 35 U.S.C. 112 ¶1

Claims 67-73, 75-81, and 96 were further rejected under 35 U.S.C. 112 ¶1 for lack of enablement. The Office Action, at pages 6-7, suggests that the claims are directed to detecting cancer by detecting a response against *all* of the protein family members of Hey/HRT, but that the specification teaches only that an autoimmune response against *no more than one* member of the Hey/HRT protein family will be detected. The Office Action concludes that, since all Hey/HRT proteins are to be detected, but no more than one could be detected, the claims are not enabled.

There is no limitation, however, in the claim to only Hey/HRT proteins and therefore the Office Action's limitation of the claimed invention to only Hey/HRT proteins is, respectfully, incorrect. When the claimed invention is considered as a whole, the interpretation of the claim as allowing testing only for Hey/HRT is manifestly contrary to reason because the specification clearly teaches testing a variety of transcription factors, with the Hey/HRT family being only one such factor.

The limitation to Hey/HRT proteins is argued in the Office Action as being justified by the Patent Office's restriction practice. The Patent Office has instituted restriction practice for various purposes but provides no basis for using restriction practice to narrowly construct the

claims for purposes of patentability analysis. It is respectfully submitted that restriction practice in this case calls for a search of transcription factors that include at least one Hey/HRT protein, wherein the factors are involved in testing a sample obtained from the host for an autoimmune response against the plurality of transcription factors. In the absence of prior art involving Hey/HRT, other transcription factors that are involved in the claimed testing would then be searched.

The Examiner is therefore requested to withdraw this rejection on the grounds that the claims are not limited to testing all and only Hey/HRT proteins, so that the enablement rejection is moot.

Response to rejections for lack of written description under 35 U.S.C. 112 ¶1

Claims 67-73, 75-81, and 96 were further rejected under 35 U.S.C. 112 ¶1 for lack of written description because of the limitation of a "cancer condition" lacks support. For clarity, the term "cancer condition" has been amended to recite "cancer". The as-filed application describes various cancerous conditions as being the object of testing, e.g., as in Example 2, entitled "Antibodies against transcription factors in the blood of subjects with small cell and non small cell lung cancer - a clinical study". In the clinical study of Example 2, referring to clinical data obtained from human patients suffering from cancer, the testing and diagnosis of "non-small cell lung cancer (NSCLC)" and "small cell lung cancer (SCLC)" is described at length. The repeated references to cancer and cancer types provides support for the limitation to "cancer". Since the disputed term has been amended, the withdrawal of this rejection is requested.

Response to rejections for anticipation under 35 U.S.C. 102(b).

Claims 67-73, 75-78, and 80-81 were further rejected under 35 U.S.C. 102(b) as being anticipated by Stockert et al. The Office Action describes Stockert et al. as teaching testing a

cancer patient serum sample for an autoimmune antibody response against NY-ESO-1, MAGE-1, MAGE-3, SSX, and Melan-A wherein the cancer condition is a presence of a cancer cell in a host. The Office Action points to the term "transcription modulating factor" as encompassing all moieties within a cell. By implication, NY-ESO-1, MAGE-1, MAGE-3, SSX, and Melan-A would therefore be a "transcription modulating factor".

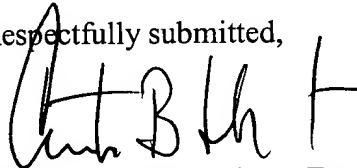
The present claims are directed to a "transcription factor". Stockert et al. apparently does not teach that NY-ESO-1, MAGE-1, MAGE-3, SSX, or Melan-A is a transcription factor. Therefore Stockert et al. does not meet all of the presently claimed limitations and withdrawal of this rejection is requested.

Conclusion

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Curtis B. Herbert', with a stylized flourish at the end.

Curtis B. Herbert, Ph.D., Esq.
Registration No. 45,443

Customer No. 24113
Patterson, Thunte, Skaar & Christensen, P.A.
4800 IDS Center
80 South 8th Street
Minneapolis, Minnesota 55402-2100
Telephone: (612) 349-3008